Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A method for production of a human proteinaceous therapeutic molecule comprising:

(a) ~~identify~~ identifying a mammalian cell line derived from a tissue that produces the proteinaceous therapeutic molecule in nature;

(b) transfecting a plurality of cells from the mammalian cell line with a gene coding for the human proteinaceous therapeutic molecule;

(c) cloning the transfected cells expressing the human proteinaceous therapeutic molecule;

(d) expanding the cloned cells in a rotating cell culture system filled with a culture ~~media~~ medium, wherein the rotating cell culture system provides a simulated micro-gravity environment for the expanding cloned cells and a membrane carrier assembly transverses a growth compartment, the membrane carrier comprising a support cylinder having a first end in communication with a fluid inlet and a second end in communication with a fluid outlet, a molecular weight cut-off membrane secured to an exterior surface of the support cylinder, and a medium circulation chamber between the exterior surface of the cylinder and an interior surface of the membrane, the chamber in fluid communication with the fluid inlet and the fluid outlet;

(e) growing the cloned transfected cells in the rotating cell culture system, wherein the cloned cells synthesize the human protein and secrete the human protein into the culture medium in the rotating cell culture system;

(f) separating a volume of culture ~~media~~ medium from the expanded cloned cells; and

(~~f~~g) isolating a protein fraction from the volume of culture ~~media~~ medium, wherein the protein fraction is rich in the proteinaceous therapeutic molecule.

2. (original) The method of claim 1, wherein the human proteinaceous therapeutic molecule is post-translationally modified.

3. (original) The method of claim 1, wherein the human proteinaceous therapeutic molecule is PP14.

4. (original) The method of claim 1, wherein the mammalian cell line is a human derived cell line.

5. (original) The method of claim 3, wherein the mammalian cell line is a human myelomous leukemia cell line.

6. (original) The method of claim 1, wherein the gene coding for the human proteinaceous therapeutic molecule includes a bioselection mechanism.

7. (currently amended) The method of claim ~~5~~ 6, wherein the bioselection mechanism is ~~an antibiotic~~ a Blasticidin S HCl resistance.

8. (original) The method of claim 1, wherein the gene coding for the human proteinaceous therapeutic molecule includes a polyhistidine fusion tag.

9. (original) The method of claim 1, wherein the rotating cell culture system provides a low-shear environment equal to 2 dynes/cm^2 or less.

10. (original) The method of claim 1, wherein the rotating cell culture system rotates from about 10 rpm to about 20 rpm.

11. (canceled)

12. (currently amended) The method of claim ~~11~~ 1, wherein the molecular weight cut-off membrane has a molecular weight cut-off value that is greater than the molecular weight of the human proteinaceous therapeutic molecule.

13. (original) The method of claim 11, wherein the molecular weight cut-off membrane has a molecular weight cut-off value that is less than the molecular weight of the human proteinaceous therapeutic molecule.

14. (original) The method of claim 1, further comprising the step of providing a continuous flow of the culture media to the cloned cells in the rotating cell culture system.

15. (original) The method of claim 14, wherein the continuous flow of culture media is oxygenated through an external gas exchange membrane.

16. (currently amended) The method of claim 1, wherein the protein fraction is isolated using a column material designed to remove serum albumin from the culture ~~media~~ medium.

17. (original) The method of claim 8, wherein the protein fraction is isolated using a metal chelate column.

18. (currently amended) A method for the production of recombinant human proteins comprising:

(a) selecting a post-translationally modified human protein;

(b) identifying a human cell line derived from a tissue that produces the human protein;

(c) transfecting a plurality of cells from the human cell line with a gene coding for the human protein and a gene coding for a bioselection mechanism;

(d) cloning the transfected cells expressing the human protein and the bioselection mechanism;

(e) introducing the cloned transfected cells into a rotating cell culture system filled with a culture ~~media~~ medium, wherein the rotating cell culture system has a membrane carrier assembly transversing a growth compartment, the membrane carrier comprising a support cylinder having a first end in communication with a fluid inlet and a second end in communication with a fluid outlet, a molecular weight cut-off membrane secured to an exterior surface of the support cylinder, and a medium circulation chamber between the exterior surface of the cylinder and an interior surface of the membrane, the chamber in fluid communication with the fluid inlet and the fluid outlet; and

(f) growing the cloned transfected cells in the rotating cell culture system, wherein the cloned cells synthesize the human protein and ~~excrete~~ secrete the human protein into the culture ~~media~~ medium in the rotating cell culture system.

19. (original) The method of claim 18, wherein the human protein is PP14.

20. (original) The method of claim 18, wherein the human cell line is human myelomous leukemia cell line.

21. (original) The method of claim 18, wherein the bioselection mechanism is an antibiotic resistance.

22. (canceled)

23. (currently amended) A method for the production of recombinant human proteins comprising:

(a) selecting a post-translationally modified human protein;

(b) identifying a human cell line derived from a tissue that produces the human protein;

(c) transfecting a plurality of cells from the human cell line with a gene coding for the human protein and a bioselection mechanism;

(d) cloning the transfected cells expressing the human protein and the bioselection mechanism;

(e) providing a culture chamber comprising

(i) a tubular housing;

(ii) a growth compartment within the housing;

(iii) a fluid inlet;

(iv) a fluid outlet; and

(v) a membrane carrier assembly transversing the growth compartment including a support cylinder having a first end in communication with the fluid inlet and a second end in communication with the fluid outlet, a molecular weight cut-off membrane secured to an exterior surface of the support cylinder, and a medium circulation chamber between the exterior surface of the cylinder and an interior surface of the membrane, the chamber in fluid communication with the fluid inlet and the fluid outlet ~~horizontally rotating cell culture system having a molecular weight cut-off membrane transversing a growth chamber of the cell culture system, wherein the rotating cell culture system provides a low shear environment less than or equal to 2 dynes/cm^2~~;

(f) introducing the cloned transfected cells into the growth chamber of the rotating cell culture system filled with a culture media;

(g) maintaining a flow of the culture media through the growth chamber of the rotating cell culture system;

(h) expanding the cloned transfected cells in the rotating cell culture system, wherein the cloned cells synthesize the human protein and ~~excrete~~ secrete the human protein into the culture ~~media~~ medium in the rotating cell culture system;

(i) separating the cloned transfected cells from a volume of the culture ~~media~~ medium containing the ~~excrete~~ secreted human protein; and

(j) isolating a protein fraction from the volume of the culture ~~media~~ medium, wherein the protein fraction is rich in the human protein.

24. (original) The method of claim 23, wherein the molecular weight cut-off membrane has a molecular weight cut-off value that is less than a molecular weight of the human protein.

25. (original) The method of claim 24, wherein the human protein accumulates in the growth chamber of the rotating cell culture system.

26. (currently amended) The method of claim 23, wherein the protein fraction is isolated using a column material designed to bind and remove albumin from the volume of culture ~~media~~ medium without binding and removing the human protein from the volume of culture media.